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December 18, 2018

VIA FOIAONLINE.REGULATIONS.GOV

George Bollweg, Ph.D.
U.S. Environmental Protection Agency Region 5
Air and Radiation Division
77 West Jackson Boulevard
Mail Code: AT-18J
Chicago, IL 60604-3507
Bollweg.George@epa.gov

**Re: Request for Information Pursuant to the Freedom of Information Act,
40 C.F.R. Part 2 and 2 C.F.R. § 1500.1**

Dear Dr. Bollweg:

This is a request for records of the U.S. Environmental Protection Agency (“EPA”) pursuant to the Freedom of Information Act, 5 U.S.C. § 552, 2 C.F.R. § 1500.1, and 40 C.F.R. Part 2. Please send all responsive records to the following address:

Joseph J. Green
Kelley Drye & Warren LLP
3050 K Street NW
Suite 400
Washington, D.C. 20007-5108
JGreen@KelleyDrye.com

I request all of the research data generated by any researchers conducting research on EPA’s behalf pursuant to Cooperative Agreement Number 83416001 and EPA Contracts EP-11-D-000424 and EP-13-D-000146 (hereinafter “Ohio Research”). Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues.

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Based on EPA's response to MIG's 2017 FOIA request seeking the same research data (*i.e.*, EPA-R5-2017-007986), the data MIG seeks can be found in two separate "files" as set forth below:

- EPA dataset 7.21.16, CSV File, July 21, 2016 (hereafter "EPA dataset 1"); and
- EPA_Medication_Dataset 7.21.16, CSV File, July 21, 2016 (hereafter "EPA dataset 2").

According to the "codebooks" for these two datasets disclosed by EPA in its response to FOIA Request EPA-R5-2017-007986, EPA dataset 1 is comprised of 1529 separate data "variables" (in the column so labeled in the xl file), while EPA dataset 2 is comprised of 395 separate data "variables" (also in the column so labeled in the xl file).

MIG is aware that EPA has previously asserted that disclosure of EPA datasets 1 and 2 "would constitute a clearly unwarranted invasion of personal privacy." However, that earlier determination was made without reference to guidance issued by the federal government's Department of Health and Human Services ("HHS") which makes abundantly clear that the redaction of data fields linked to the identity of the research participants would allow EPA to release the health information generated as part of the Ohio research because the resulting information *would no longer be protected health information*.¹ It necessarily follows that any such redacted disclosure by EPA cannot reasonably be deemed to constitute a clearly unwarranted invasion of personal privacy.

To be clear, moreover, MIG is not asking EPA to create any new documents (as EPA claimed to be the case in its response to FOIA Request EPA-R5-2019-000086). By MIG's estimation, the following numbered variables for each dataset (designated by its corresponding "position" in the column so-labeled in the xl file) may contain personal information that potentially may need to be redacted in order for EPA to disclose the datasets consistent with the HHS De-identification Guidance:

- EPA dataset 1: Variable 1 (participant's ID); variables 992-1011 (relating to participants employment), variables 1117-1120 (relating to participant's health insurance) and variable 1121 (name of primary care physician).
- EPA dataset 2: Variable 1 (participant's ID); Variables 170 and 172-173 (relating to participant's health insurance).

¹ See Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, U.S. Department of Health and Human Services (November 26, 2012)(hereafter "HHS De-identification Guidance"), p. 6 ("the Privacy Rule does not restrict the use or disclosure of de-identified health information, as it is no longer considered protected health information.") available at <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification>.

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The redaction of an existing EPA document does not constitute creation of a new document. As is made abundantly clear from information contained at www.foia.gov, EPA redacts documents disclosed in responses to FOIA requests with considerable frequency.

As set forth in the Office of Management and Budget's guidance for financial assistance to non-Federal entities (*i.e.*, 2 C.F.R. § 200.315(e)(1)), the foregoing research was (a) produced under a Federal award and (b) used by the Federal Government in developing agency action that has the force and effect of law in connection with Clean Air Act enforcement proceedings initiated by the United States government on EPA's behalf against S.H. Bell Company. *See United States v. S.H. Bell Company*, Civil Action No. 4:17-cv-00131-BYP, U.S. District Court for the Northern District of Ohio Eastern Division.²

If the estimated cost for responding to this request exceeds \$500, please contact me prior to proceeding with the request. I thank you advance for your assistance. If you have any questions concerning this request, please do not hesitate to contact me. Please do not hesitate to contact me, as counsel to MIG, at 202.342.8849 or JGreen@KelleyDrye.com.

Respectfully submitted,



Joseph J. Green
Counsel to the Manganese Interest Group

cc: National Freedom of Information Officer
U.S. Environmental Protection Agency
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² *See United States' Memorandum in Support of Motion for Entry of Consent Decree* (March 28, 2017) available in PACER: Case: 4:17-cv-00131-BYP, Doc #: 7 Filed 03/28/17 19 of 23 PageID #: 99 ("Nor can there be any real doubt that the peer-reviewed RARE grant health study finding a correlation between manganese exposure and manganism symptoms in East Liverpool residents supported bringing this case.").